

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA AB and
ASTRAZENECA PHARMACEUTICALS
LP,

Plaintiffs,

V.

ALEMBIC PHARMACEUTICALS LTD.,
and ALEMBIC PHARMACEUTICALS,
INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively “AstraZeneca” or “Plaintiffs”), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants Alembic Pharmaceuticals Ltd. (“Alembic India”) and Alembic Pharmaceuticals, Inc. (“Alembic USA”) (collectively, “Alembic” or “Defendant”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 208576 (“ticagrelor ANDA”) filed by Defendant with the U.S. Food and Drug Administration (“FDA”) for approval to market 60 mg and 90 mg generic versions of AstraZeneca’s BRILINTA® (ticagrelor) drug product prior to expiration of AstraZeneca’s U.S.

Patent No. 10,300,065 (“the ’065 patent”), that is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) for BRILINTA®.

PARTIES

2. AstraZeneca is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail against serious diseases, including treatments for cardiovascular diseases.

3. Plaintiff AstraZeneca AB is a company operating and existing under the laws of Sweden, with its principal place of business at SE-151 85 Södertälje, Sweden. AstraZeneca AB is the owner of the ’065 patent.

4. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at One MedImmune Way, Gaithersburg, Maryland 20878. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application (“NDA”) No. 022433 for BRILINTA® (ticagrelor). AstraZeneca Pharmaceuticals LP markets and sells BRILINTA® in this judicial district and throughout the United States. Defendant specifically directed a letter dated August 2, 2022 with the heading “Re: Notification of Certification Under 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug & Cosmetic Act, and Under 21 C.F.R. § 314.95 Alembic Pharmaceuticals Ltd. – Ticagrelor Tablet 90 mg ANDA No. 208576” (“Notice Letter”) to AstraZeneca Pharmaceuticals LP.

5. On information and belief, Alembic India is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India. On information and belief, Alembic India, itself and through its affiliates and subsidiaries, including Alembic USA, formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

6. On information and belief, Alembic USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Highway 202, Bridgewater, New Jersey 08807. On information and belief, Alembic USA is a wholly-owned subsidiary and U.S. agent of Alembic India.

7. On information and belief, Alembic USA is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

8. On information and belief, Alembic USA is qualified to do business in Delaware and appointed a registered agent for service of process, by filing with the Secretary of State on August 10, 2012 pursuant to sections 371 and 376 of title 8 of the Delaware Code: (1) a certificate of incorporation as a domestic corporation, under file number 5197177; and (2) a statement naming “National Registered Agents, Inc.” located at 1209 Orange Street, Wilmington, Delaware, 19801, as its registered agent to accept service of process in the State of Delaware.

9. On information and belief, Defendant developed the proposed generic products that are the subject of the ticagrelor ANDA to seek regulatory approval from FDA to market and sell the proposed ANDA products throughout the United States, including within Delaware.

10. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of the ticagrelor ANDA, Defendant will distribute and sell the generic products described in the ticagrelor ANDA throughout the United States and within Delaware.

JURISDICTION AND VENUE

11. Each of the preceding paragraphs 1 to 10 is re-alleged and re-incorporated as if fully set forth herein.

12. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

14. On information and belief, venue is proper in the District of Delaware for Alembic India because it is an Indian corporation “not resident in the United States” that accordingly “may be sued in any judicial district” for venue purposes. 28 U.S.C. § 1391(c)(3); *see also In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018) (reaffirming the “long-established rule that suits against aliens are wholly outside the operation of all the federal venue laws, general and special” (quoting *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 714 (1972))).

15. On information and belief, venue is proper in the District of Delaware for Alembic USA because it is incorporated in Delaware, and thus the District of Delaware is the judicial district “where the defendant resides.” 28 U.S.C. § 1400(b); *see also TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 581 U.S. ___, 137 S. Ct. 1514, 1521 (2017) (“[a]s applied to domestic corporations, ‘reside[nce]’ in § 1400(b) refers only to the State of incorporation”).

16. Alembic India is subject to specific personal jurisdiction in this District based on the filing of its ticagrelor ANDA with a Paragraph IV certification regarding the ’065 patent. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762-63 (Fed. Cir. 2016).

17. As in *Acorda*, Alembic India “has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at,” on information and belief, this District and elsewhere. *Acorda Therapeutics*, 817 F.3d at 759.

18. Alembic India’s “ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs.” *Acorda Therapeutics*, 817 F.3d at 760.

19. As in *Acorda*, on information and belief Alembic India, alone and/or in concert with its agent, Alembic USA, “intends to direct sales of its drugs” into this District, among other places, “once it has the requested FDA approval to market them.” *Acorda Therapeutics*, 817 F.3d at 758.

20. On information and belief, Alembic India, alone and/or in concert with its agent, Alembic USA, will engage in marketing of its proposed ticagrelor ANDA products in Delaware, upon approval of its ticagrelor ANDA.

21. Alembic India’s ANDA filing, including its Paragraph IV certifications regarding the ’065 patent at issue here, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities in this District by Defendant.

22. “[T]he minimum-contacts standard is satisfied by the particular actions [Defendant] has already taken—its ANDA filing[]—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct” in this District. *Acorda Therapeutics*, 817 F.3d at 760.

23. On information and belief, Alembic India and Alembic USA hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

24. On information and belief, Alembic India and Alembic USA work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products in the District of Delaware and throughout the United States.

25. On information and belief, Alembic India and Alembic USA acted in concert to develop the proposed generic products that are the subject of the ticagrelor ANDA to seek regulatory approval from FDA to market and sell the proposed ANDA products in the District of Delaware and throughout the United States.

26. On information and belief, Alembic India and Alembic USA work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products in the District of Delaware and throughout the United States.

27. In the Notice Letter, Defendant notified AstraZeneca Pharmaceuticals LP that it had submitted its ticagrelor ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letter states that it “is provided by Alembic, by and through the undersigned authorized representative, to whom any inquiry, reply or other correspondence should be addressed.” The Notice Letter was sent by Alembic to AstraZeneca Pharmaceuticals LP in the United States, specifically in this District.

28. On information and belief, the preparation and submission of the ticagrelor ANDA by Alembic India was done at the direction, under the control, in concert with, and/or for the direct benefit of Alembic USA.

29. Further, on information and belief, Alembic India and Alembic USA will manufacture, market, and/or sell within the United States the generic products described in the

ticagrelor ANDA if FDA approval is granted. If the ticagrelor ANDA is approved, on information and belief the generic products would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

30. Furthermore, Alembic India and Alembic USA have both previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and have availed themselves of Delaware courts through the assertion of counterclaims. *See, e.g., AstraZeneca AB et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:21-cv-00875-RGA; *Amgen Inc. et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:21-cv-00061-CFC; *Otsuka Pharm. Co., Ltd. et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:20-cv-01365-LPS; *AbbVie Inc. et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:20-cv-01009-LPS; *AstraZeneca AB et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:20-cv-00202-RGA; *Novartis Pharm. Corp. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:20-cv-00074-LPS; *Otsuka Pharm. Co., Ltd. et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:19-cv-02007-LPS; *CyDex Pharm., Inc. v. Alembic Global Holding SA et al.*, C.A. No. 1:19-cv-00956-LPS; *Genentech, Inc. et al. v. Alembic Pharm., Ltd. et al.*, C.A. No. 1:19-cv-00177-RGA; *Boehringer Ingelheim Pharm. Inc. et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:18-cv-01762-CFC; *H. Lundbeck A/S et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:18-cv-00113-LPS; *Wyeth LLC et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:16-cv-01305-RGA; *Bayer Pharma AG et al. v. Alembic Pharm. Ltd. et al.*, C.A. No. 1:15-cv-00832-GMS; *Sanofi et al. v. Alembic Pharm. Ltd.*, C.A. No. 1:14-cv-00424-RGA; *Teijin Ltd. et al. v. Alembic Pharm. Ltd.*, 1:13-cv-01939-SLR; *Pfizer Inc. et al. v. Alembic Ltd. et al.*, 1:11-cv-01213-GMS.

31. Alembic India and Alembic USA have also availed themselves of Delaware courts by filing cases in this District as plaintiffs. *See, e.g., Alembic Pharm. Ltd. et al. v. GlaxoSmithKline LLC et al.*, C.A. No. 1:18-cv-01513-RGA.

32. This Court also has personal jurisdiction over Alembic India and Alembic USA because, *inter alia*, Alembic India and Alembic USA have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Alembic India and Alembic USA regularly and continuously transact business within the state of Delaware, including by selling pharmaceutical products in Delaware, directly and/or through affiliates, and/or by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware. On information and belief, Alembic India and Alembic USA derive substantial revenue from the sale of those products in Delaware and have availed themselves of the privilege of conducting business within the State of Delaware.

33. For example, on information and belief, on August 10, 2012, Alembic USA was incorporated in the State of Delaware as a “domestic” corporation under file number 5197177.

34. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Alembic India and Alembic USA.

PATENT-IN-SUIT

35. On May 28, 2019, the U.S. Patent and Trademark Office duly and legally issued the '065 patent, entitled “Method of treating or prevention of atherothrombotic events in patients with history of myocardial infarction.” A true and correct copy of the '065 patent is

attached hereto as **Exhibit A**. The claims of the '065 patent are valid and enforceable.

AstraZeneca AB is the owner of the '065 patent by assignment and has the right to enforce it.

36. AstraZeneca Pharmaceuticals LP is the holder of NDA No. 022433 by which FDA granted approval for the marketing and sale of ticagrelor tablets in 90 mg and 60 mg dosage strengths, to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome (ACS) or a history of myocardial infarction (MI), to reduce the risk of stent thrombosis in patients who have been stented for treatment of ACS, and to reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events. AstraZeneca markets ticagrelor tablets in the United States, through AstraZeneca Pharmaceuticals LP, under the trade name "BRILINTA®." FDA's official publication of approved drugs, the Orange Book, includes BRILINTA® in 90 mg and 60 mg dosage strengths together with Orange Book-listed patents protecting BRILINTA® and its use, including the '934 and '065 patents.

INFRINGEMENT BY DEFENDANT

37. Each of the preceding paragraphs 1 to 36 is re-alleged and re-incorporated as if fully set forth herein.

38. In the Notice Letter, Alembic notified AstraZeneca Pharmaceuticals LP that it had submitted its ticagrelor ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

39. The Notice Letter states that Alembic is seeking approval from FDA to engage in the commercial manufacture, use, and sale of 90 mg generic ticagrelor tablets before the expiration of, *inter alia*, the '065 patent. On information and belief, in combination with a second Notice Letter sent by Alembic to AstraZeneca Pharmaceuticals LP on September 8, 2020

pertaining to 60 mg generic ticagrelor tablets (*see* C.A. No. 21-875-RGA, D.I. 1), Alembic intends to engage in the commercial manufacture, use, and sale of its 60 mg and 90 mg generic ticagrelor tablets after receiving FDA approval to do so.

40. In the Notice Letter, Alembic notified AstraZeneca that its ANDA contained a “Paragraph IV certification” asserting that the ’065 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Alembic’s generic ticagrelor tablets.

41. This Complaint is being filed before the expiration of the forty-five days from the date AstraZeneca received the Notice Letter.

COUNT I (INFRINGEMENT OF THE ’065 PATENT)

42. Each of the preceding paragraphs 1 to 41 is re-alleged and re-incorporated as if fully set forth herein.

43. Defendant’s submission of its ticagrelor ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 60 mg and 90 mg generic ticagrelor tablets prior to the expiration of the ’065 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

44. On information and belief, upon FDA approval of Defendant’s ticagrelor ANDA, Defendant will further infringe at least claim 1 of the ’065 patent by making, using, offering to sell, and selling its 60 mg and/or 90 mg generic ticagrelor tablets in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

45. Defendant, in its Notice Letter, provides no relevant factual basis for contending that its ticagrelor ANDA product will not infringe the claims of the '065 patent under 35 U.S.C. §§ 271(a), 271(b), or 271(c).

46. Defendant's alleged non-infringement position is premised on the fact that "none of the end users" of Defendant's 90 mg ticagrelor tablets would infringe the claims of the '065 patent, which require administration of a 60 mg tablet of ticagrelor. According to Defendant, AstraZeneca's patent rights in the '065 patent are allegedly exhausted once AstraZeneca, and not Defendant, sells the 60 mg ticagrelor tablets to patients.

47. Defendant's position ignores that its Notice Letter incorporates its previous September 8, 2020 Notice Letter by reference, which was directed to 60 mg ticagrelor tablets.

48. Defendant has filed a single ANDA No. 208576 seeking FDA approval to engage in the commercial manufacture, use, offer to sell, or sale of 60 mg and 90 mg generic ticagrelor tablets prior to the expiration of the '065 patent.

49. Accordingly, upon FDA approval, on information and belief Defendant would market both 60 mg and 90 mg generic ticagrelor tablets to patients throughout the United States, including Delaware.

50. If Defendant's marketing and sale of 60 mg and 90 mg generic ticagrelor tablets prior to expiration of the '065 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca respectfully prays that this Court grant the following relief:

1. A judgment that the claims of the '065 patent are not invalid, not unenforceable, and are infringed by Defendant's submission of its ticagrelor ANDA, and that Defendant's

making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's 60 mg and 90 mg generic ticagrelor tablets will infringe the '065 patent.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Defendant's ticagrelor ANDA shall be a date which is not earlier than the latest expiration date of the '065 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

3. An order permanently enjoining Defendant, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendant's 60 mg and 90 mg generic ticagrelor tablets until after the latest expiration date of the '065 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

4. Damages or other monetary relief to AstraZeneca if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Defendant's 60 mg and 90 mg generic ticagrelor tablets prior to the latest expiration date of the '065 patent, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: September 16, 2022

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